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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,131	02/13/2002	Babu J. Mavunkel	219002028310	9859
25225	7590	07/26/2004	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/076,131	MAVUNKEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celia Chang	1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 39-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 39-71 and 75-78 is/are rejected.
- 7) ☐ Claim(s) 72-74 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. This application is a RCE of SN 10/076,131. The after final amendment dated Feb. 27, 2004 have been entered. Claims 1-38 have been canceled. Claims 39-78 are pending. The version of specification received by the PTO dated Aug. 8, 2003 which has been verified by the attorney of record is now the copy of specification under consideration.

2. Claims 39, 75-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39, the term R4 is "alkyl and aryl optionally including one or more heteroatoms selected from O,S and N" is indefinite and unclear. What does including mean? Heteroaromatic? Or substituted with heteroatom containing moiety? it is unclear of what chemical structure is this term referring to.

Claim 75, "a condition characterized by a proinflammation response" is unclear as to what condition this is. What is the character determining whether the condition is within the scope or not within the scope. In addition, the intended coverage of the scope encompassed those character and conditions which will be correlated in future discovery to be related to proinflammation, thus, is a "reach through" scope.

Claim 76, "said condition characterized by inflammation" is confusing and lacks antecedent basis in the base claim since the base claim is drawn to proinflammatory response. Claim 77-78 have the same problem wherein no antecedent basis of the "said" condition can be found in the base claim. Please note that clinically, proinflammatory response is not inflammation (see Cecil textbook of medicine, disorders of inflammatory response). The scope of the claims are very confusing.

3. Claims 39-71, 75-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The factors to be considered herein are those set forth as the *In re Wands*, 8 USPQ 2<sup>nd</sup> 1400 (1988) decision.

*Nature of invention*

The scope of claim 1 wherein R4 is "alkyl and aryl optionally including one or more heteroatoms selected from O,S and N" lacks sufficient descriptive and enabling support in the specification. No explicit description can be found as to what the intended chemical structure is for such terms.

*The state of the art and predictability*

The state of the art indicated that the substituents on the bicyclic moieties are important features independently and distinct responsible for the utility of the chemical products. For example, it is evidenced that when R4 is aryl including four nitrogen, the compounds have activity in treating proliferative disease (CA 139:117268). When the substituents on the bicyclic ring wherein R4 is hydrogen, X1 is sulfonyl (CA 131:67650), the compounds have thrombin inhibition activity. Therefore, the drastic diversity in utility resulted from small chemical structure all fall within the claimed scope indicated the high degree of unpredictability of such compounds.

*The amount of guidance and working examples*

A survey of the specification revealed that none of the X1 is sulfonyl compounds has been made or tested to have p38 kinase activity. None of the compounds wherein R4 is broadly "aryl" including heteroatoms has been made or tested to have p38 kinase activity.

In view of the diversity of utility based on the bicyclic core with distinct substitution as evidenced supra, the lacking of variation for the Markush scope with such breadth finds the claimed scope lacks description as well as enablement.

In addition, were applicants' proinflammatory response including diseases such as arthritis, a 102(f) or (g) issue may have to be resolved with the CA 139:117268 reference.

4. Claims 72-74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
July 22, 2004

A handwritten signature in black ink, appearing to read 'Celia Chang'.

Celia Chang  
Primary Examiner  
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